

CANNON BUILDING 861 SILVER LAKE BLVD., SUITE 203 DOVER, DELAWARE 19904-2467

# STATE OF DELAWARE BOARD OF PHARMACY

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PUBLIC MEETING NOTICE: BOARD OF PHARMACY

DATE AND TIME: Wednesday, September 16, 2015 9:30 am

PLACE: Conference Room A, 2<sup>nd</sup> Floor Cannon Building

861 Silver Lake Blvd., Dover, DE 19904

APPROVED: Approved 10/21/15

## **MEMBERS PRESENT**

Susan Esposito, R.Ph., Professional Member, President Hooshang Shanehsaz, R.Ph., Professional Member, Vice President Kimberly Robbins, R.Ph., Professional Member Tejal Patel, PharmD, Professional Member Bonnie Wallner, R.Ph., Professional Member Julia Wheatley, Public Member Jay Galloway, Public Member

## **MEMBERS ABSENT**

Joli Martini, R.Ph., Professional Member Kenneth Sellers, Public Member

### **DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT**

David Dryden, Executive Secretary Eileen Kelly, Deputy Attorney General Christine Mast, Administrative Specialist III Michelle McCreary, Pharmacist Compliance Officer

## **ALSO PRESENT**

Timothy Dillon

Jaime Frink

Mike Oznick

Mike Reitehie

**Brad Spooling** 

Robert Voyles

**David Coronito** 

Steve Seurer

Scott Anderson

Suzanne Raab-Long

Jeanne Chigzone

**Emily Schaffer** 

James Xa

Joel Lueking

Joe Lavino

**Amy Buter** 

Elizabeth Ryan Tiffany Sorey Dot Hart Janis Lert

## **CALL TO ORDER**

Ms. Esposito called the meeting to order at 9:30 a.m.

## **REVIEW OF MINUTES**

A motion was made by Mr. Shanehsaz and seconded by Ms. Wallner, to approve the meeting minutes for June 17, 2015 with provided corrections. The motion unanimously carried.

### PRESIDENT'S REPORT

Ms. Esposito welcomed the members of the board and the public.

She stated that she would be appointing Mr. Shanehsaz to the Collaborative Care Committee.

Ms. Esposito stated that the new USP800 information has been released and would like to see a committee formed in the future to review the information and how it affects Delaware.

## **UNFINISHED BUSINESS**

## Complaint Status

- 13-09-11 Assigned to Hearing Officer
- 13-12-11 Assigned to Hearing Officer
- 13-19-11 Forwarded to Office of Attorney General
- 13-01-13 Forwarded to Office of Attorney General
- 13-04-13 Forwarded to Office of Attorney General
- 13-05-13 Forwarded to Office of Attorney General
- 13-06-13 Forwarded to Office of Attorney General
- 13-20-13 Forwarded to Office of Attorney General
- 13-26-13 Assigned to Hearing Officer
- 13-01-14 Forwarded to Office of Attorney General
- 13-03-14 Assigned
- 13-04-14 Assigned
- 13-05-14 Assigned
- 13-06-14 Forwarded to Office of Attorney General
- 13-07-14 Forwarded to Office of Attorney General
- 13-08-14 Assigned
- 13-09-14 Forwarded to Office of Attorney General
- 13-10-14 Forwarded to Office of Attorney General
- 13-11-14 Forwarded to Office of Attorney General
- 13-12-14 Forwarded to Office of Attorney General
- 13-13-14 Assigned
- 13-14-14 Forwarded to Office of Attorney General
- 13-15-14 Assigned
- 13-16-14 Assigned
- 13-17-14 Assigned

#### Re-Review Tabled Application

Avella of Deer Valley – a motion to approve the application was made by Ms. Robbins seconded by Mr. Galloway. The motion unanimously carried.

Blessings International – a motion to approve the application was made by Ms. Robbins seconded by Mr. Galloway. The motion unanimously carried.

Cantrell Drug Company – a motion to table the application was made by Ms. Robbins seconded by Mr. Galloway. The motion unanimously carried.

# Propose to Deny Hearing

APL Logistics, a motion to accept the applications for the locations in California and Wisconsin was made by Mr. Shanehsaz seconded by Mr. Galloway. APL Logistics requested withdrawal of applications received for locations in Georgia and Pennsylvania.

## Deliberations on Proposed Changes to Regulation 5.1.7 and 10.0

Ms. Kelly brought the hearing to order. No public comment or written comment was received during the hearing held on August 19, 2015. The written comment period was held open for an additional 15 days. The following comments received during the open comment period were marked as exhibits and presented to the Board for review:

- 1. Email from Richard N. Spencer, Jr., VMD, White Clay Creek Veterinary Hospital, dated 9/2/15
- 2. Letter from Tracey Barkus, LVT, VCA Newark Animal Hospital, received 8/31/15
- 3. Letter from Melanese Jones, LVT, VCA Newark Animal Hospital, dated 8/26/15
- 4. Letter from Jennifer Arculus, DVM, VCA Newark Animal Hospital, dated 8/27/15
- 5. Letter from Shelly Boulware, VCA Newark Animal Hospital, dated 8/26/15
- 6. Letter from Amy Haines, LVT, VCA Newark Animal Hospital, dated 8/31/15
- 7. Letter from, Pecos Olurin, MD, et al., Delaware Academy of Ophthalmology, dated 9/2/15
- 8. Email from Joseph P. Olekszyk, DO, Nanticoke Ear, Nose and Throat, dated 9/3/15
- 9. Letter from Tarek S. Hassan, MD, et al., American Society of Retina Specialists, received 9/3/15
- 10. Letter from Alfonse Muto, RPh, Pine Pharmacy, dated 9/3/15
- 11. Letter from Michael Teixido, MD, et al., ENT & Allergy of Delaware, dated 9/3/15
- 12. Letter from Terri Corbo, PharmD, et al., Christiana Care Health Services, dated 8/21/15
- 13. Letter from David W. Dryden, RPh., JD, Executive Secretary, Delaware Board of Pharmacy, dated 9/2/15

The Board members reviewed the comments received. The Board determined that the proposed changes to regulation 10.0 could move forward. A motion was made by Ms. Robbins seconded by Mr. Shanehsaz to approve the proposed changes to regulation 10.0.

A motion was made to reject the proposed changes to regulation 5.7.1 and republish the regulation by Ms. Robbins seconded by Mr. Shanehsaz. The motion carried.

The Board continued deliberations and determined that substantive changes would need to be made to proposed regulation 5.1.7. The Board discussed amending regulation 5.1.7.1 to state that <u>non-patient specific compounded products may not be sold to a practitioner for office use unless covered under federal authority.</u> A motion was made by Mr. Shanehsaz seconded by Ms. Robbins to accept the new language. The motion carried.

A public hearing will be held on October 21, 2015 at 9:30 a.m. in the second floor conference room A of the Cannon Building, 861 Silver Lake Boulevard, Dover, Delaware regarding the substantive changes made to 5.1.7 of the regulations as stated above.

### Statutory and Regulatory Discussion

- Practitioner/Pharmacy Ownership No Report
- Provision for Disciplinary Action No Report
- Pharmacy Technician Regulation No Report
- Clarification of §2512(e)(f), Inactive Status No Report
- Review of Crimes Listing currently in review by the legislative committee

#### Re-Review Hearing Officer Recommendation

This Recommendation was re-reviewed due to the circumstance that Mr. Dillon attended the last meeting to offer exceptions but did not realize that he could speak up. He was therefore afforded opportunity to address the Board. Mr. Dillon offered comments regarding the Hearing Officer's recommended sanctions. After reviewing the Recommendation and considering Mr. Dillon's comments, a motion was made by Mr. Shanehsaz seconded by Ms. Robbins to modify the recommendation to reflect 2 years' probation effective immediately. Mr. Dillon will have 120 days to fulfill the requirements of the recommendation. The motion carried with Ms. Wallner recusing herself.

### **NEW BUSINESS**

## **Public Hearing Proposed Changes to Regulation 3.8**

Ms. Kelly called the hearing to order. The Board members introduced themselves for the record. The purpose of the meeting is for the board to consider adoption of proposed amendments to rules and regulations. The proposed changes effect regulation 3.8. Ms. Kelly submitted exhibits of public hearing notices that were published in the Delaware State News and the News Journal. There being no public comment, the hearing was adjourned. The written comment period will be held open for another 15 days. Ms. Kelly asked that deliberations of proposed regulations be added to the October 21, 2015 agenda.

### Capsa Solutions First Dose Device and Pharmerica- RXNow Device Review

Capsa Solutions First Dose Device, a motion to approve use of this device was made by Mr. Shanehsaz seconded by Ms. Patel. The motion carried unanimously.

Pharmerica - RXNow Device, a motion to approve use of this device was made by Ms. Robbins seconded by Mr. Shanehsaz. The motion carried.

## Ms. Esposito read into the record the following ratifications:

### Pharmacist and Intern Licensure Approval Ratifications

## Pharmacist:

A1-0004804	Jarjeet Giovonni Singh
A1-0004805	Michelle Louise Link
A1-0004806	David A. Gajdosik
A1-0004807	Jonathan Calvert Feathers
A1-0004808	Beth E. Koven
A1-0004809	Rushita Y. Patel
A1-0004810	Ali I. Alqaisi
A1-0004811	Oghenekevwe L. Aziza
A1-0004812	Selorm Kodzo Woadzro
A1-0004813	Mercy Fonyi Mudoh
A1-0004814	Barbara Kwakye-Safo
A1-0004815	Bronessa Sylvia Fernandes
A1-0004816	Michael A. Rabinowitz
A1-0004817	Brenda L. Matthews
A1-0004818	Daniel J. Purzycki
A1-0004819	Kelsey Alyssa Trichilo
A1-0004820	Darci Mukendi
A1-0004821	Calvin Tran
A1-0004822	Elizabeth Colleen Stancliffe
A1-0004823	Theresa Donkor
A1-0004824	Carl H. Gerdine
A1-0004825	Bethran C. Nnorom
A1-0004826	Christine Ly
A1-0004827	Chelsea O'Brien
A1-0004828	Rachael Elizabeth McWilliams
A1-0004829	Michelle Adamczyk

A1-0004830 Miral M. Patel
A1-0004831 Andrew Thomas Johnson
A1-0004832 Lauren Ashley Muller
A1-0004833 Trisha Rose Hernandez
A1-0004834 Desiree N. Massari

A motion was made by Mr. Galloway and seconded by Ms. Patel to approve the ratification of the Pharmacist applications. The motion unanimously carried.

## **Pharmacist Intern:**

None

## Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001677 Reliable Pharmacy, LLC

A9-0001678 Primary Care Pharmacy

A9-0001679 South Coast Specialty Compounding, Inc DBA Park Compounding

A9-0001680 Best Care Pharmacy Inc.

A9-0001681 Homescripts.com, LLC

A9-0001682 Prescription Care Pharmacy, LLC

A9-0001683 Care Direct RX, LLC

A9-0001684 AnazaoHealth Corporation

A9-0001685 Rx Care Providers Corp. dba Echo Pharmacy

A9-0001686 Speedyrx, LLC

A9-0001687 Glen Rock Medical Pharmacy

A9-0001688 Time Square Drugs, Inc.dba Manhattan's Pharmacy

A9-0001689 Care Partners Medical, LLC

A9-0001690 Keystone Rx

A9-0001691 Coram Healthcare Corporation of Greater D.C., DBA Coram CVS/specialty Infusion Services

A9-0001692 Hawthorn Drug Group, Inc.

A9-0001693 BriovaRx

A9-0001694 Pharmacy Link, Inc.

A9-0001695 MedPharma, LLC

A9-0001696 Healthy Meds Pharmacy Corp.

A9-0001697 Red Chip of Nevada

A9-0001699 Crescent Drug Corp. dba Echo Drugs

A9-0001700 MedicoRX Specialty Pharmacy

A9-0001701 Catamaran Home Delivery

A9-0001702 Catamaran Home Delivery

A9-0001703 BriovaRx

A motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

## Wholesale Distributor Licensure Approval Ratifications

A4-0002231 Alvix Laboratories LLC

A4-0002232 BioRx

A4-0002233 RecoverCare, LLC

A motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

### Medical Gas Dispensers

A2-0000132 Advanced Medical Homecare Supplies, Inc.

A2-0000133 Linde Gas North America LLC

A2-0000134 American HomePatient

A2-0000135 US Med, LLC

A motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to approve the ratification of the Medical Gas Dispensers applications. The motion unanimously carried.

#### Retail Pharmacy Licensure Approval Ratification

A3-0000988 Delaware CVS Pharmacy, L.L.C. dba CVS/Pharmacy 10238 A3-0000989 Metro Pharmacy Inc.

A motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

# Retail Pharmacy Temporary Licensure Approval Ratification

None

## **Outsourcing Facility**

AA-0000012 AnazaoHealth Corporation

A motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to approve the ratification of the Outsourcing Facility applications. The motion unanimously carried.

## Pharmacist-In-Charge Interviews

Ms. Robbins conducted PIC interviews with: Emily Schaffer, Nemours Outpatient Pharmacy James Xu, Walgreens #11011 Wilmington, De

## Board Review of Applications by DAG

Care Direct Rx, a motion to approve was made by Ms. Robbins seconded by Ms. Patel. The motion carried. Trilogy Pharmacy, a motion to propose to deny was made by Mr. Shanehsaz seconded by Ms. Robbins. The motion carried unanimously.

Anazao Health Corp., a motion to approve was made by Mr. Shanehsaz seconded by Ms. Robbins. The motion carried unanimously.

Prescription Care Pharmacy, a motion to approve was made by Mr. Galloway seconded by Ms. Martini. The motion carried unanimously.

Cantrell Drug Co., a motion to table was made by Ms. Robbins seconded by Ms. Patel. The motion carried unanimously.

Trigen Laboratories; a motion to table was made by Ms. Esposito seconded by Ms. Robbins. The motion carried unanimously.

Rx Care Providers Corp., a motion to approve was made by Ms. Esposito seconded by Ms. Robbins. The motion carried unanimously.

IV Solutions of Lubbock, a motion to table was made by Ms. Esposito seconded by Ms. Wheatley. The motion carried unanimously.

South Coast Specialty Compounding, a motion to approve was made by Ms. Robbins seconded by Mr. Galloway. The motion carried unanimously.

Best Care Pharmacy, a motion to approve was made by Ms. Robbins seconded by Mr. Galloway. The motion carried unanimously.

Blessings International, a motion to table was made by Ms. Esposito seconded by Ms. Robbins. The motion carried unanimously.

Homescripts.com LLC., a motion to approve was made by Ms. Robbins seconded by Ms. Patel. The motion carried unanimously.

Doctor's Specialty Pharmacy, a motion to table was made by Mr. Shanehsaz seconded by Ms. Esposito. The motion carried unanimously.

Empire Specialty Pharmacy, a motion to table was made by Ms. Esposito seconded by Ms. Patel. The motion carried unanimously.

Lisa White, a motion to approve was made by Mr. Shanehsaz seconded by Ms. Martini. The motion carried unanimously.

## Continuing Education Approval

None

#### **COMMITTEE REPORTS**

Legislative - Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz and David Dryden

The committee continues to review the current crimes listing in comparison to similar healthcare professions. The next scheduled meeting will be on October 21, 2015 immediately following the Board of Pharmacy meeting.

**Continuing Education** — Joli Martini, Bonnie Wallner, Tejal Patel and David Dryden:

No Report

Consumer Affairs - Ken Sellers, Jay Galloway and Julia Wheatley

No Report

Professional Liaisons - Kim Robbins and Tejal Patel:

Liz Ryan from DPS reported the last meeting was conducted on September 15, 2015. DPS is currently in the process of completed a schedule of continuing education trainings that will be available.

Controlled Substance Liaisons - Kenneth Sellers, Tejal Patel, Jay Galloway and David Dryden:

Mr. Dryden reported that the committee continues to work on the Safe Opioid Prescribing regulations. The next scheduled meeting is on September 23, 2015.

Patient Safety Committee - Michelle McCreary (Chair), Kenneth Sellers, Tejal Patel, Kimberly Robbins, Susan Esposito, Joli Martini, Hooshang Shanehsaz, Jay Patel

No Report

#### COMMITEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee - Tejal Patel, Brenda Pavlic, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

The board requested that this agenda item be retired from the agenda.

**Collaborative Care Committee** – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:

No Report

#### **BOARD CORRESPONDENCE**

None

# EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim

Mr. Dryden reported that he will be attending the National Association of State Controlled Substance Authorities (NASCSA) meeting scheduled to be held in October.

There will be a meeting at the National Boards of Pharmacy in October that Ms. Patel will attend in New Hampshire.

Mr. Dryden reported that there has been staff changes occurring over the last few weeks which have slowed response times to inquiries a bit.

Ms. McCreary reported that she has completed the following inspections:

- 1 Inspection with the DEA which resulted in a total of 5 visits
- 3 Opening Inspections
- 1 Remodel Inspection
- 1 Relocation Inspection
- 1 Medical Gas Dispenser Inspection
- 1 Inspection with FDA
- 1 Re- Inspection

#### **NEWSLETTER UPDATES**

No Report

# OTHER BUSINESS BEFORE THE BOARD

None

# **PUBLIC COMMENT**

None

# **NEXT SCHEDULED MEETING**

The next meeting is scheduled for October 21, 2015 at 9:30 Am., Conference Room A 2<sup>nd</sup> floor.

## **ADJOURNMENT**

There being no other business before the Board a motion to adjourn the meeting was made by Ms. Patel, seconded by Ms. Robbins at 12:45 pm. The motion unanimously carried.

Respectfully submitted,

**Christine Mast** 

Administrative Specialist III

Liaison, Board of Pharmacy